NOV 2 6 2003

K033561

FUJIFILM
I&I - Imaging & Information

FUJIFILM MEDICAL SYSTEMS USA, INC.

419 WEST AVENUE
STAMFORD, CT 06902
Telephone: 203/324-2000
Fax: 203/353-0926

510(K) Summary

In accordance with the requirements of the Safe Medical Device Act, FUJIFILM Medical Systems, USA, Inc. herewith submits a 510(K) summary of safety and effectiveness for the following device.

SUBMITTER NAME / ADDRESS: FUJIFILM Medical Systems, USA, Inc.
419 West Avenue
Stamford, CT 06902

CONTACT PERSON / TEL NO: Frank Gianelli
Regulatory Coordinator
Tel No: (203) 602-3774

DATE SUMMARY PREPARED: August 21, 2003

ESTABLISHMENT NO.: 2443168

TRADE/PROPRIETARY NAME: ***Fuji Computed Radiography (FCR) Velocity***

COMMON/USUAL NAME: Computed Radiography Image Reader

CLASSIFICATION NAME: Solid State X-Ray Imager

CLASS/PANEL: Class II, 90-MQB, 21CFR 892.1650

PREDICATE DEVICE(S): Fuji FCR 9501-HQ

DEVICE DESCRIPTION:

A Fuji Computed Radiography (FCR) system typically consists of an image reader (IR), patient ID terminal, imaging plates (IPs), IP cassettes, interface board, positioning monitor, laser printer for hard copy output, and optionally an image workstation, optical disk file, and network interface. **This notification is for the image reader and associated imaging plates.** IPs are used as two-dimensional radiation detectors in place of radiographic film and intensifying screens to capture a portion of the projected x-ray patient image in space. In the image reader, the captured image data is associated electronically with patient and exam identification data and the latent image is read by laser emission by the phenomenon of photostimulable luminescence. The photostimulated luminescence is collected, detected, sampled, and digitized. The image data is then digitally processed according to exam and user-specified parameters and may be displayed on a CRT monitor to confirm patient positioning, printed by a hard copy device (such as laser printer, or dry printer), or output to a workstation, optical disk file, or other destination. The device performs no lossy compression of image data.

FCR Velocity consists of an Image Reader and an Imaging Plate (described below). The Image Reader is cassetteless because the Image Plate is built into the upright exam stand configuration of the FCR Velocity Image Reader. Imaging plates are exposed via conventional X-ray devices. The X-ray irradiated IP is then moved from the exposure position to the reading position, and images are read. After reading, the IP is erased, and moved to the exposure position again.

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As with other FCR image readers, the FCR Velocity will feature a photostimulable phosphor imaging plate (IP) composed of europium activated barium fluorohalaid compounds in a crystal form held in an organic binder. The IP used with the subject device will have a rigid substrate, which enables it to be held in a constant plane. IPs are used as two-dimensional radiation detectors in place of radiographic film and intensifying screens to capture a portion of the projected x-ray patient image in space. In the image reader, the captured image data is associated electronically with patient and exam identification data and the latent image is read by laser emission by the phenomenon of photostimulable luminescence. The photostimulated luminescence is collected, detected, sampled, and digitized. The image data is then digitally processed according to exam and user-specified parameters and may be displayed on a CRT monitor to confirm patient positioning, printed by a hard copy device (such as laser printer, or dry printer), or output to a workstation, optical disk file, or other destination. The device performs no lossy compression of image data.

INTENDED USE:

The Fuji Computed Radiography (FCR) Velocity Image Reader with Image Plate (IP) reading is intended to be used for the identification, capture, digitization, and processing of diagnostic x-ray images, and associating patient and exam identification with the images.

PREDICATE DEVICE AND SUBSTANTIAL EQUIVALENCE INFORMATION:

FCR Velocity is considered comparable and substantially equivalent to the FCR 9501-HQ Image Reader manufactured by Fuji. FCR 9501-HQ has been granted a 510(k) clearance. Refer to accession number K951373.

PARAMETER	FUJI FCR VELOCITY U		FUJI FCR 9501HQ	
Image Recording				
Patient Identification	Digital Data (from Console)		Digital Data (from Console)	
Recording Method	Photostimulable Luminescence		Photostimulable Luminescence	
No. of Imaging Plates Used	One Built-in Imaging Plate		Four Built-in Imaging Plates	
Imaging Plate Size	497x456 mm		495x377 mm	
Image Reading				
Reading Laser	Laser Diodes (658 nm)		He-Ne Laser (675 nm)	
Gray Scale	10 bits (1024 gray levels)		10 bits (1024 gray levels)	
Sampling Raster	IP Reading Area	Pixels/mm	IP Reading Area	Pixels/mm
	17x17 in.	10	N/A	
	17x14 in.	10	N/A	
	14x17 in.	10	14x17 in.	10
	14x14 in.	10	14x14 in.	10
	10x12 in.	10	10x12 in.	10
	12x10 in.	10		
	8x10 in.	10	8x10 in.	10
	10x8in.	10		
	18x43 cm	10	N/A	
Physical				
WxHxD (mm)	645x1835x450 (Image Reader)		1163x1733x935 (Image Reader)	
Weight (kg)	220		580	
Throughput (Approximate)	240 14x17 in. IP's/hr.		80 14x14 in. IP's/hr	
Processing Time	80 seconds		132 seconds	

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SAFETY INFORMATION:

FCR Velocity introduces no new safety and efficacy issues other than those already identified with the predicate device. The results of a hazard analysis, combined with the appropriate preventive measures taken indicate that the device is of minor level of concern as per the May 29, 1998 issue of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

FCR Velocity complies with the following mandatory and voluntary standards:

- 21 CFR 1040.10 - Performance Standards for Light Emitting Products (Laser Products)
- 21 CFR 1020.30 - Performance Standards for Ionizing Radiation Emitting Products (Diagnostic X-ray System and their Major Components)
- Medical Electrical Equipment Part 1: General Requirements for Safety UL Standard 60601-1 (IEC 60601-1-1 included)
- Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests: IEC 60601-1-2

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

FUJIFILM Medical Systems USA, Inc.
% Mr. William J. Sammons
Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive, P.O. Box 13995
Research Triangle Park, NC 27709-3995

AUG 23 2013

Re: K033561
Trade/Device Name: Fuji Computed Radiography (FCR)
Velocity Image Reader (CR-IR364)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: November 5, 2003
Received: November 12, 2003

Dear Mr. Sammons:

This letter corrects our substantially equivalent letter of November 26, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

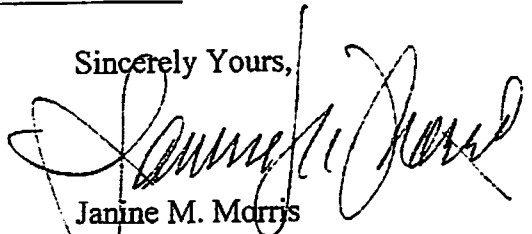
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033561

Device Name : **FCR Velocity Image Reader (CR-IR364)**

Indications For Use :

The indications for use of the Fuji Computed Radiography (FCR) Velocity Image Reader with Image Plate (IP) reading is the identification, capture, digitization, and processing of diagnostic x-ray images, and associating patient and exam identification with the images.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legan

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033561

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109

(Optional Format 1-2-96)